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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,005	07/03/2003	Juergen Andrew Kortenbach	06530.0170-05	3367

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,005

Applicant(s)KORTENBACH, JUERGEN
ANDREW**Examiner**

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/3/03;12/30/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 3/18/05</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and Species I in the reply filed on 14 June 2006 is acknowledged. The traversal is on the ground(s) that Applicant has not necessarily agreed with Examiner's assertions concerning the allegedly distinct claimed inventions and species. This is not found persuasive because each of the inventions is distinct since the apparatus as claimed is can be used to practice another and materially different process such as one that requires a surgical incision. Also, each of the species is patentably distinct from the other and do not overlap in scope and are not obvious variants of each other. Therefore these alternative inventions and structures would require more than a single search in view of different classification and would impose a burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 3 July 2003 is acknowledged. In addition, the IDS submitted on 30 December 2004 and the IDS submitted on 18 March 2005 are also acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

3. The abstract of the disclosure is objected to because it exceeds 150 words.

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 110, 117, 120-122, 124-127, 129, 130 and 135 are rejected under 35 U.S.C. 102(b) as being anticipated by **Harrison et al.** (U.S. Patent No. **5,403,326**).

Claims 110, 129, and 130: Harrison et al. discloses a surgical instrument comprising an elongated tube **80** having a proximal end for extending outside of the body and a distal end for positioning proximate multiple tissue layers, a distal member coupled proximate the distal end of the tube and configured to fold a fundus of a stomach toward an esophageal wall or multiple tissue layers together, and a grasper **72** configured to grasp at least a portion of the fundus or esophageal wall, wherein the grasper is coupled to one of the elongated tube and the distal member (Figure 9 and col. 7, lines 24-26).

Claims 117 and 127: Harrison et al. discloses a control member or actuator **86,88** configured to control operation of at least one of the distal member and the grasper **72** used for engagement between male and female members of a fastener (see

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explanation for Claim 125 below), the control member **86,88** located or coupled proximate the proximate end of the tube (col. 8, lines 1-10).

Claim 120: Harrison et al. discloses the at least a portion of the fundus or the esophageal wall grasped by a grasper **72** is a gastroesophageal junction (col. 7, lines 65-68).

Claim 121: Harrison et al. discloses a method of performing invagination, which comprises providing the surgical instrument of claim 110, inserting the surgical instrument transorally into a stomach, grasping a portion of the fundus or the esophageal wall with the grasper, and folding the fundus toward the esophageal wall with the distal member, while grasping the portion of the fundus or the esophageal wall (col. 3, lines 13-24).

Claim 122: Harrison et al. discloses a grasper **72** which is integrally formed with the distal member (Figure 9).

Claims 124 and 135: Harrison et al. discloses applying a fastener **90** with the distal member to secure the fundus to the esophageal wall or multiple tissue layers (col. 8, lines 23-30).

Claim 125: Harrison et al. discloses the fastener having a male member **92,94** and a female member **96**, and the distal member including a first part configured to hold the male member and a second part coupled to the first part and configured to hold the female member in opposed relation with the male member (Figure 8C).

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Claim 126: Harrison et al. discloses rotating at least one of the first and second parts with respect to the other of the first and second parts so as to cause engagement between the male and female members (Figures 8C and 8D).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 111-116, 118, 123, 131-134, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Harrison et al.** (U.S. Patent No. **5,403,326**) in view of **Huitema et al.** (U.S. Patent No. **5,562,701**).

Claims 111-114, 116, 123, 131-134, and 136: Harrison et al. discloses the claimed device, including a grasper **72** being located between two members, a first grasping member **66** and second grasping surface **66** associated with the first grasping surface so as to grasp the at least the portion of the fundus or esophageal wall or the multiple tissue layers therebetween, and a fastener having a first part **92,94** and a second part **96** (Figure 8C), except for the distal member including a stationary member and a rotatable member rotatably coupled to the stationary member..

Huitema et al. teaches a stationary member **412** and a rotatable member **414** rotatably coupled to the stationary member, the rotatable member member rotatably movable with respect to the stationary member between an open position capable of

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receiving at least a portion of a fundus and the esophageal wall and a closed position for folding the fundus of the stomach toward the esophageal wall or for folding multiple tissue layers therebetween (Figure 21 and col. 21, lines 1-11). Huitema et al. teaches that this jaw configuration is desirable when the working area is confined and can be incorporated in instruments with relatively small cross sections (col. 1, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a stationary member and a rotatable member rotatably coupled to the stationary member, as taught by Huitema et al., to Harrison et al., in order to be used in confined working spaces.

Claim 115: Harrison et al. discloses the distal member being configured to deploy a fastener **90** to the folded fundus and esophageal wall. See explanation for Claims 124 and 125 in paragraph 5 above.

Claim 118: Harrison et al. discloses the claimed device except for one control cable extending from the control member to at least one of the distal member and the grasper through the tube.

Huitema et al. teaches the use of a control cable **440** that is connected to the distal member and extends to the control member (col. 21, lines 20-31). Huitema et al. teaches that the use of control cables are advantageous as tension members and their loop construction is beneficial when using certain brittle cord materials (col. 4, lines 11-35). It would have been obvious to one of ordinary skill to provide a control cable, as taught by Huitema et al., to Harrison et al. in order to actuate the distal member by using tension and allowing for use of certain materials that are susceptible to brittleness.

8. Claims 119 and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Harrison et al.** (U.S. Patent No. **5,403,326**) in view of **Stevens et al.** (U.S. Patent No. **5,797,960**).

Claims 119 and 128: Harrison et al. discloses the claimed device except for the tube including a port for an endoscope at its proximal end.

Stevens et al. teaches an endoscope being inserted into the proximal end of an elongated tube at a port **90**, in order for there to be visualization, and it is known in the art that incorporating endoscopes with surgical instruments allows for less invasive surgery by having the surgeon view the surgical site via the endoscope (col. 21, lines 63-67). It would have been obvious to one of ordinary skill in the art to provide an endoscope port at the proximal end of an elongated tube, as taught by Stevens et al., to Harrison et al. in order to allow for visibility during fundoplication.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Laufer et al.** (U.S. Patent No. **6,835,200**) discloses a method for fixating the wall of the stomach to the wall of the esophagus for treatment of GERD; **Matsui et al.** (U.S. Patent No. **6,835,200**) discloses an endoscopic surgery apparatus with tissue grasping elements.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER